

FY 2004 PROGRAM ELEMENT EVALUATION REPORT

OF THE

PLANT SANITATION PROGRAM ELEMENT SHELLFISH SANITATION PROGRAM DEPARTMENT OF MARINE RESOURCES STATE OF MAINE

PREPARED BY

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ON

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PROGRAM ELEMENT EVALUATION REPORT

STATE: Maine

DATES OF EVALUATION: February 17 - 20, 2004 and March 10 - 12, 2004

PROGRAM ELEMENT EVALUATED: Plant Sanitation

A. Status of Deficiencies from Last Program Evaluation

The FY 2003 evaluation of the Maine Department of Marine Resources (DMR) Plant Sanitation Program found that DMR was in non-compliance with three (3) items found in the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The Plant Sanitation Program was also provided with nine (9) recommendations cited to help the state strengthen its program. The recommendations were addressed in the state's response to the PEER dated August 20, 2003.

Below are the three non-conformities noted in the FY 2003 evaluation followed by the states response to each item:

- 1) During a review of the central files in Hallowell it was noted that the minimum inspection frequency is not being met. In the past 12 months, the Depuration facility was missing two required monthly inspections, three Shucker-packers were missing one or more required quarterly inspections and a Shellstock Shipper was missing one semi-annual inspection.
 - Audits will be conducted quarterly on all certified dealer's files to make sure that the inspection frequency is being met. A report will be generated based on this audit and submitted to the Division Director.
- 2) During a review of the central files in Hallowell it was noted that follow-up inspections are not being completed in a timely fashion in order to verify compliance. These compliance schedules are agreed upon by the facility management and the inspector during the completion of the inspection. Inspectors must complete the follow-up inspection on (or shortly thereafter) the agreed upon date in order to verify that a facility has corrected all recorded deficiencies.

A Standard Operation Procedure (SOP) was developed to address how many 'Key' and 'Other' violations trigger a follow-up inspection. The SOP will also address when the inspectors should return to the firm, i.e. 30 days, the next routine inspection, etc. Internal policy was established directing the inspectors to return to the facility within 21 days of the agreed upon compliance schedule correction completion date.

3) During a review of the central files in Hallowell it was noted that when an enforcement method was selected it was not accompanied by documentation explaining why that particular option was selected. When the timely follow-up inspection determines that a facility has not complied with the compliance schedule the inspector must document the next most appropriate course of action, i.e. revise the compliance schedule, suspend or revoke certification or seek other administrative remedies.

As part of the SOP described in #2 above, the inspection supervisor is charged with reviewing the completed inspection forms to ensure that compliance schedule extensions are properly documented.

The DMR have repeatedly presented new regulation to the state legislature in an attempt to restrict the sale of newly harvested shellstock to only those certified dealer listed in the Interstate Certified Shellfish Shippers List (ICSSL). The DMR have recently written new regulation in an attempt to direct the activities of shellfish harvesters themselves. These requirements of harvesters, although existing in the Guide for the Control of Molluscan Shellfish, are being applied to Commercial Shellfishermen for the first time. Once the new regulations are adopted they will considerably strengthen the time/temperature controls on newly harvested shellstock leaving the designated growing areas.

B. Total Number and Identification of Plants Evaluated

The number of certified firms listed in the February 1, 2004 ICSSL was utilized in determining the number of firms selected for FY 2004 evaluation activities. The February 1, 2004 ICSSL indicated that Maine had 122 shellfish plants certified: 1 Depuration Processor, 28 Shucker-Packers, 82 Shellstock Shippers and 11 Reshippers. Thirteen firms were selected for the joint FDA/DMR evaluation inspections as required by Attachment D in the FY 2004 FDA Molluscan Shellfish Compliance Program (CP). Maine does not have any certified firms conducting post harvest processing activities.

The selection of plants was conducted by DMR Shellfish Plant Inspection Personnel. The selection of plants was conducted the latter part of January 2004. Final selections were based on geographic location and availability. Field evaluations of the selected firms were conducted the week of February 17, 2004 and on March 10, 2004. A file review of the 13 facilities evaluated was conducted at the Central Office in Hallowell, ME on March 11 and 12, 2004. Certified firm name, certification number and date of inspection are listed below.

Certified Firm Name	Certification #	Date of Inspection
Perkins Seafood	ME-323-SP	02/17/2004
Moody Seafood	ME-55-SS	02/17/2004
J & A Seafood	ME-180-SS	02/17/2004
Durham Seafood	ME-90-SS	02/17/2004
Robbins Clams	ME-262-SP	02/18/2004
Mill River Seafood	ME-171-SP	02/18/2004
Tinky's Seafood	ME-251-SP	02/18/2004
Young's Shellfish	ME-321-SP	02/19/2004
Young's Lobster Pound	ME-222-SP	02/19/2004
L & J Seafood	ME-61-SP	02/20/2004
Grant's Seafood	ME-177-SP	02/20/2004
Spinney Creek Shellfish, Inc.	ME-271-DP	03/10/2004
Douty Brothers, Inc.	ME-115-SS	03/10/2004

C. State Program Areas in Compliance and Program Areas Evaluated

Program Administration/Legal Authority

The Maine Department of Marine Resources is in the process of adopting the recently released 2002 NSSP Model Ordinance portion of the <u>Guide for the Control of Molluscan Shellfish</u>, with only minor exceptions. The DMR currently does not have the legal authority to enforce the NSSP HACCP requirements. The inspectors are however, documenting HACCP violations during routine inspections.

The SSO, Bruce Chamberlain, and Shellfish Inspectors Jeffrey Armstrong and Jerry Bishop continue to work with certified firms to fully implement the Seafood HACCP regulations. They have distributed HACCP notebooks with examples of HACCP plans, SSOPs, monitoring forms and daily sanitation records. The notebooks are provided to the firm's management/staff during the annual HACCP training sessions which the firms are required to attend.

There were three critical deficiencies identified at three separate certified facilities during this evaluation. The first violation was observed at Robbins Clams (ME-262-SP) on 2/18/2004. It was noted that the hose used to fill the hot-dip cool-down tank remained submerged in the tank when not in use to fill the tank. The backflow concern was explained to the facility's management and the hose was removed from the tank and returned to the hose storage wall bracket. The second violation was observed at Young's Shellfish (ME-321-SP) on 2/19/2004. It was noted that corrective actions were not documented when the cooler temperature exceeded

the critical limits specified in the HACCP Plan. The proper documentation procedure was explained to the facility's management. The third violation was observed at L & J Seafood (ME-61-SP) on 2/20/2004. It was noted that the cooler temperature was 53 degrees Fahrenheit and the clams located in the cooler which were shucked the previous day had an internal temperature of 51 degrees Fahrenheit. Cooler temperature monitoring procedures were explained to the facility's management and 38 gallons of shucked clams were confiscated and destroyed. All 'Key' and 'Other' deficiencies noted during this evaluation were either corrected during the inspection or are being corrected as part of a compliance schedule developed by the DMR and plant management.

The State of Maine has not been the original source of shellfish associated with any *Vibrio vulnificus* (*V.v.*) illness in the past three years. Maine was the possible source of one *Vibrio parahaemolyticus* (*V.p.*) illness. A thirty year old female consumed soft shell clams as an appetizer, along with a broiled seafood platter as the main course, on July 3, 2002 with an illness onset on July 5, 2002. The suspect clams were harvested from the Sheepscot River in Maine. No additional V.p. illnesses have been reported since the July 3, 2002 illness. The DMR currently operates under Time-Temperature Matrix Option 3 - Level 2 year round.

Time-Temperature Matrix

ACTION LEVEL	AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
LEVEL 1	<66 °F (18 °C)	36 hours
LEVEL 2	66 °F - 80 °F (19 °C - 27 °C)	24 hours
LEVEL 3	> 81 °F (> 27 °C)	20 hours

HACCP Implementation and General Sanitation

The thirteen certified shellfish plants evaluated in Maine were all in possession of a properly formatted and complete HACCP Plan. The DMR have achieved a moderate level of HACCP compliance (monitoring and verification) within their certified facilities. The DMR conduct mandatory workshops for the managers of the shellfish facilities. The facility managers are also encouraged to have their employees attend these informative training sessions. During the workshop, the DMR staff present the HACCP notebook which contains customized HACCP plans, standardized forms and other related information to aid in HACCP education. The notebooks contain all of the information needed to comply with the NSSP MO HACCP requirements. The Inspection Staff also provide detailed in-plant training in hopes of achieving a high level of compliance in regards to the actual implementation of the plan's monitoring and record keeping sections. As new firms request certification, or when there is staff turnover within the facility, the SSO and/or other standardized inspectors provide the notebooks and training as needed. Despite the level of effort listed above, 54% of the facilities are unable to properly verify their receiving records once every seven days. Refer to Attachment A for specific numbers found in this section.

The inspection form consists of two additional sections: the <u>Key Sanitation</u> items (8 thru 16) and the <u>Other Model Ordinance Requirements</u> which deal with the general facility condition, management and sales records (17 thru 30). It was noted during the field evaluations that Key Sanitation Item #9 - "Condition and cleanliness of food contact surfaces", was debited at 8 of the 13 firms (62%). It was noted that the next most commonly found Key Sanitation debits were for Items #10 - "Prevention of cross-contamination" and #11 - "Maintenance of hand-washing, hand sanitizing, and toilet facilities", at 4 of the 13 firms (31%).

The general facility requirements (17 thru 30) experienced the most debits under two distinct items. Item #17 - "Plants and Grounds", received debits at 10 of the 13 firms (77%) and Item #18 - "Plumbing and related facilities", received debits at 9 of the 13 firms (69%).

Standardization/Maintenance

The Maine DMR Shellfish Standardization Officer (SSO) Bruce Chamberlain conducted standardization inspections with the FDA in February 2004. The firms inspected and the disagreement results of these standardization inspections can be found in the table below. Mr. Chamberlain's average composite score based on the five formal standardization inspections is within the acceptable average score required to achieve standardization. In fact, Mr. Chamberlain's performance has improved since his last assessment in June of 2000.

FIRM NAME	НАССР	SANITATION ITEMS	ADDITIONAL MO REQUIREMENT
Perkins Seafood - ME-323-SP	1	1	1
February 17, 2004	1	1	1
Robbins Clams - ME-262-SP	1	1	2
February 18, 2004	1	1	2
Tinky's Seafood - ME-251-SP	0	2	2
February 18, 2004	U	2	3
Young's Lobster Pound - ME-222-SP	0	1	1
February 19, 2004	U	1	1
Grant's Seafood - ME-177-SP	0	2	2.
February 20, 2004	U	2	2
TOTAL	2	7	9
	/5	/5	/5
*Average Score	0.4	1.4	1.8
Acceptable Avg. Score	3	3	4

INSPECTIONAL EQUIPMENT	<u>SATISFACTORY</u>	NEEDS IMPROVEMENT
COMMUNICATION	<u>SATISFACTORY</u>	NEEDS IMPROVEMENT

The DMR SSO utilizes the NSSP <u>Plant Standardization Procedures</u> guidelines to standardize all other state shellfish plant inspectors.

D. Current Deficiencies

Certified Shellfish Shipper Deficiencies

Observed nonconformities with NSSP requirements for certified firms are indicated on the NSSP Standardized Shellfish Processing Plant Inspection Form (93-01(A)) completed by FDA Northeast Regional Shellfish Specialist Peter N. Koufopoulos for each firm evaluated during FY 2004 and are on file. The table below is a breakdown of the Firms evaluated during this visit; along with the number of debits noted on the First page of the inspection form. The "Total Page 2" column shows the actual total number of various debits listed on the Narrative page of the inspection form. This column was added to show the total number of deficiencies noted since the First page could have multiple deficiencies under a single item number. Certified firm deficiencies are summarized by code in the table below and are listed by checklist deficiency and firm classification in Attachment A.

Certified Firm Name		Number of Violations					
		Critical	Key	Other	Total	Total Page 2	
Perkins Seafood	ME-323-SP	0	7	2	9	12	
Moody Seafood	ME-55-SS	0	5	0	5	11	
J & A Seafood	ME-180-SS	0	5	0	5	9	
Durham Seafood	ME-90-SS	0	6	1	7	13	
Robbins Clams ME-262-		1	6	2	9	12	
Mill River Seafood	ME-171-SP	0	4	0	4	4	
Tinky's Seafood	ME-251-SP	0	4	2	6	8	
Young's Shellfish	ME-321-SP	1	10	6	17	23	
Young's Lobster Pound ME-222-SP		0	4	2	6	7	
L & J Seafood	ME-61-SP	1	9	2	12	17	
Grant's Seafood	ME-177-SP	0	4	2	6	10	
Spinney Creek Shellfish, Inc.	ME-271-DP	0	1	2	3	3	
Douty Brothers, Inc.	ME-115-SS	0	3	2	5	5	

The individual inspection forms completed by the Regional Shellfish Specialist are included as Attachment B. The five inspections used as part of the joint program evaluation and restandardization of the SSO are noted directly on Page 1 of the inspection forms.

State Inspection Program Evaluation Criteria

a) All dealers are required to be properly certified in accordance with the Guide for the Control of Molluscan Shellfish.

The DMR requires all firms to apply for initial certification and recertification in accordance with NSSP MO Chapter I.@.02. All firms must meet the standards for certification and/or recertification and also demonstrate their ability to properly implement their HACCP program. The state of Maine exceeds the certification requirements by not allowing any carry over deficiencies from the previous certification period.

b) 95% of the certified dealers must be evaluated with an inspection frequency, which is compliant with the current Guide for the Control of Molluscan Shellfish.

The DMR was found to be in non-compliance with this requirement. Of the 13 firms evaluated, one shucker-packer did not have two of the quarterly inspections completed. By missing two of the inspections the percent in compliance is 92 based on 1 firm out of 13. If the level on compliance is viewed as the number of individual inspections completed for the same period then the compliance is 96% (2 missed/52 possible inspections). Robbins Clams was the SP with the missing inspections. Robbins Clams is a small shucking firm which employs approximately eight shuckers. They do not maintain consistent business hours. Two attempts were made to inspect the firm. The narrative page of the inspection form located in the facility's central file documents that the inspector visited the firm and that the firm was not operating at the time of the visit. The lack of an inspection is directly related to the severe leg injury to the SSO on August 23, 2003. The SSO was hospitalized and did not report to work for nearly five months.

c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

Of the inspection reports reviewed from the central files that contained noted deficiencies, two firms did not have properly documented compliance schedules for "Key" and "Other" deficiencies. Grant's Seafood (ME-177-SP) and Young's Lobster Pound (ME-222-SP) did not have correction dates listed on the inspection form, therefore no compliance schedule was established with either of the two firms. The absence of these dates resulted in a 15% non-compliance status for the DMR.

d) States must demonstrate that they have performed proper follow-up for compliance schedules for 90% of the dealers evaluated and if the compliance schedules were not met that administrative action was taken.

The DMR was found to be in non-compliance with this requirement for the second consecutive year. The DMR inspector and the facility's management did establish a follow-up inspection date at the end of nearly all inspections. Unfortunately a re-inspection of the

facility on the mutually agreed upon date did not take place most of the time. As part of the FY 2003 evaluation the DMR submitted a corrective action which states that a timely follow-up inspection is one that was performed within three weeks (21 days) past the originally established follow-up inspection date. A review of the central files revealed that 10 of the 13 firms had follow-up inspections completed 27 to 93 days after the agreed upon compliance date. Of the 13 firms, four firms had a follow-up inspection that found that the deficiency had not been corrected by the firm and a new correction date was issued. The narrative page did not explain why the deficiency was not corrected or why the inspector extended the compliance schedule (based on information provided by the facility's management).

In short, only 23% of the facilities had timely follow-up inspections completed. This decrease in performance from the FY 2003 Evaluation may be due to the extended absence of the SSO halfway through the state's certification year. Overall, only 69% of the facilities had proper justification describing why a compliance schedule was extended.

e) All critical deficiencies have been addressed in accordance with the Guide for the Control of Molluscan Shellfish.

There were three critical deficiencies identified during this evaluation at three of the thirteen firms inspected. The DMR does require a firm to immediately correct any critical deficiency or the facility's operations affected by that deficiency are halted until the correction has been completed and verified. At the first facility, a submerged water hose presented a back siphonage concern. The hose was removed from the water tank. The second facility was not implementing proper corrective actions when the shellfish cooler was found to be in violation of the HACCP Plan's Critical Limits. The cooler temperature was within the Critical Limits during the inspection. The firm will be monitored closely over the next several inspections. The third facility experienced Shellfish cooler temperatures in excess of 53 degrees Fahrenheit during the inspection. A review of the system found that the compressor had been turned off for repairs and never turned on again. As a result, 38 gallons of shucked clams with an internal meat temperature of 51 degrees Fahrenheit and a shucked date from the day prior were confiscated and destroyed.

The DMR is currently meeting two of the five Plant Evaluation Criteria items. This evaluation is based solely on the level of performance found during the review of the central files without taking into account the debilitating accident suffered by the SSO.

State Program Deficiencies

During a review of the central files in Hallowell it was noted that follow-up inspections are not being completed in a timely fashion in order to verify compliance. These compliance schedules are agreed upon by the facility management and the inspector upon completion of the inspection. Inspectors must complete the follow-up inspection on (or shortly thereafter) the agreed upon date in order to verify that a facility has corrected all recorded deficiencies. This is a repeat program wide deficiency also noted during the FY 2003 Evaluation.

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During a review of the central files in Hallowell it was noted that when an enforcement method was selected it was not accompanied by documentation explaining why that particular option was selected. When the timely follow-up inspection determines that a facility has not complied with the compliance schedule the inspector must document the next most appropriate course of action, i.e. revise the compliance schedule, suspend or revoke certification or seek other administrative remedies. This is a repeat program wide deficiency also noted during the FY 2003 Evaluation.

E. Recommendations

No specific recommendations were made as a result of the evaluation.

F. Corrective Actions taken by the State

All critical violations found during the evaluation were corrected immediately. Other deficiencies found during the concurrent FDA/DMR inspections were addressed in action plans and details regarding the follow-up inspections will be supplied in the states response to FDA.

As part of the State Program Deficiencies noted, the SSO has improved the tracking system utilized by the DMR in their Plant Program. This tracking system has and will be reviewed monthly for compliance. As part of this review certification renewals were denied.

G. Action Plans Requested

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to complete follow-up inspections as agreed upon in the compliance schedule. Chapter I@.02.H.1.b.i requires that action be taken when a facility "fails to meet the compliance schedule." This provision can only be determined when follow-up inspections are completed in a timely fashion. Due to the amount of lapsed time between the established date of re-inspection and the date of actual re-inspection it is evident that the current process is not adequate, therefore a new/better procedure must be proposed.

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to document on the inspection form why a particular corrective action (i.e. revise the compliance schedule, suspend or revoke certification or seek other administrative remedies) was selected in accordance with Chapter I@.02.H.1.b.ii.

H. Program Accomplishments

The Maine DMR is in the process of finalizing their re-write of the state's shellfish regulations. As part of this process, various members of the Public Health Division are attending and conducting Public Information Meetings. These meetings are being held at multiple locations around the state. Industry members have been notified and even encouraged to attend these moderated meetings in order to learn how the new regulations may affect them. These meetings allow the industry an opportunity to provide feedback on the proposed regulations at the beginning of the process. Any comments and suggestions offered by the industry members will be considered and changes can be made before the formal Public Hearings begin. The DMR have provided the industry members with an opportunity to voice their concerns, this in-turn has allowed the industry to develop a sense of ownership of the new regulations to which they will be held.

I. New or Emerging Problems

There were no new or emerging trends identified as a result of this evaluation.

J. Technical Assistance and/or Training Requested by the State

The Maine DMR Plant Sanitation Program has requested more focused field training to be conducted during FY 2005. The Regional Shellfish Specialist will work with each of the inspectors one on one to help identify those areas where improvement is possible. The additional field exercises will help the inspectors gain needed compliance in their respective facilities.

K. Conclusions

The State of Maine DMR Plant Sanitation Program does not meet all of the requirements of the NSSP Model Ordinance. The DMR continues to improve the HACCP portion of their plant inspection program. General sanitation items as well as other MO requirements have remained consistent year to year, with no appreciable improvement. A breakdown in administrative procedures has resulted in NSSP non-conformities. Corrective action plans have been requested from the Authority.

Any additional FDA follow-up will be completed at the request of FDA-CFSAN. Due to the recurring program wide deficiencies resulting from the FY 2004 Plant Sanitation Program Evaluation the DMR may be required to provide additional documentation and be subject to further scrutiny.

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L. Summary of the State's response to FDA evaluation

We concur with all of the findings in this report. It is evident that many of the changes that were put into effect over the past two years regarding timely follow-up inspections and record keeping enforcement haven't been effective. We will continue to aggressively implement existing policies and procedures, set in place to address these issues, through the performance evaluation process, through progressive discipline up to and including dismissal. We will work quickly and diligently to bring the program into compliance.

ATTACHMENT A

ATTACHMENT A.

Objectionable Conditions Cited by Plant (Total Number of Violative Firms by Type)

Item Model Ordinand	Model Ordinance	Description	code	#	Violative Firms			
Tem	Reference	Description		"	SP 8 Firms	SS 4 Firms	RS 0 Firms	DP 1 Firm
HACCP Plan	X.01.B	Presence of a HACCP Plan	С					
2. Plan Ele	ements		•				•	
2(a).	X.01.C(1)	Hazards Identified and Adequate	О	1	X			
2(b).	X.01.C(6)	Records Identified and Adequate	О					
2(c).	X.01.C(3)	Critical Limits Identified and Adequate	K					
2(d).	X.01.D(2)(c)	Signed and Dated	О					
2(e).	X.01.C(2)	Critical Control Points Identified	K	1	X			
2(f).	X.01.C(4)	Monitoring identified and Adequate	K	1	X			
2(g).	X.01.C(7)	Verification Procedures and Adequate	О	2	X	X		
2(h).	X.01.C(5)	Corrective Actions (if identified)	K	1	X			
3. HACCP	Training (Yes/No)	X.01.I	О					
4(a).	X.01.F	Receiving -Corrective Actions (c) & Records (k)	C/K					
4(a).	X.01.G	Receiving -Verification (k) & Records (k)	K	7	XXXXX	XX		
4(a).	X.01.C	Receiving -Monitoring (k) & Records (k)	K	6	XXXXX	X		
4(a).	X.01.H	Receiving - Records Format/Signed/Dated/Firm name	О	4	XX	XX		
4(b).	X.01.F	Shellstock Storage -Corrective Actions (c) & Records (k)	C/K	1	X			
4(b).	X.01.G	Shellstock Storage -Verification (k) & Records (k)	K	1	X			
4(b).	X.01.C	Shellstock Storage -Monitoring (k) & Records (k)	K					
4(b).	X.01.H	Shellstock Storage – Records Format/Signed/Dated/Firm name	О					
4(c).	X.01.F	Processing - Corrective Actions (c) & Records (k)	C/K					
4(c).	X.01.G	Processing - Verification (k) & Records (k)	K					
4(c).	X.01.C	Processing - Monitoring (k) & Records (k)	K	2	XX			
4(c).	X.01.H	Processing - Records Format/Signed/Dated/Firm name	О	1	X			
4(d).	X.01.F	Shucked Meat Storage - Corrective Actions (c) & Records (k)	C/K					
4(d).	X.01.G	Shucked Meat Storage - Verification (k) & Records (k)	K	3	XX	X		
4(d).	X.01.C	Shucked Meat Storage - Monitoring (k) & Records (k)	K	3	XXX			
4(d)	X.01.H	Shucked Meat Storage - Records Format/Signed/Dated/Firm name	0	1	X			
4(e).	X.01.F	Other Critical Limits - Corrective Actions (c) & Records (k)	C/K					
4(e).	X.01.G	Other Critical Limits - Verification (k) & Records (k)	K	1	X			
4(e).	X.01.C	Other Critical Limits - Monitoring (k) & Records (k)	K					
4(e).	X.01.H	Other Critical Limits - Records Format/Signed/Dated/Firm name	0	1	X			

ATTACHMENT A. Continued.

Item Model Ordinance	Description	code	de #	Violative Firms				
Item	Reference			SP 8 Firms	SS 4 Firms	RS 0 Firms	DP 1 Firm	
5.	XI - XIV.01.A	Approved Source Control Failure	С		8 PHHS	4 1 111118	OTHIIS	1 1 111111
6.	XI-XIV.01.B &.C	Time/Temperature Control Failure	C	1	X			
7.	NA	Other Critical Control Failure	C	1	Λ			
8.	.02.A	Safety of water for processing and ice production	C/K	2	X	X		
9.	.02.A	Condition and cleanliness of food contact surfaces	K	8	XXXXXX	XX		
10.	.02.B	Prevention of cross-contamination	C/K	4	XXXXX	AA		
11.	.02.C		C/K/O	4	XX	XX		
12.	.02.D .02.E	Maintenance of hand-washing, hand sanitizing, and toilet facilities Protection from adulterants	C/K/O	2	XX	ΛΛ		
13.				3	XXX			
	.02.F	Proper labeling, storage, and use of toxic compounds	K	3	λλλ			
14.	.02.G	Control of employees with adverse health conditions	K					
15.	.02.H	Exclusion of pests	K					
16.	.02.A.B	Sanitation Monitoring and Records	K/O	2	X	X		
	Model Ordinance Reg				T		1 [
17.	.03.A	Plants and Grounds	C/K/O	10	XXXXXX	XXX		X
18.	.03.B	Plumbing and related facilities	C/K/O	9	XXXXX	XXXX		
19.	.03.C	Utilities	C/K	1	X			
20.	.03.D	Insects and vermin control	K	4	XX	XX		
21.	.03.E	Disposal of other waste	О					
22.	.03.F	Equipment construction (non-food contact surfaces)	0	3	XXX			
23.	.03.G	Cleaning non-food contact surfaces	0	4	XXX			X
24.	.03.Н	Shellfish storage and handling	K/O	1				X
25.	.03.I	Heat shock	K					
26.	.03.J	Personnel	K/O	4	XXX	X		
27.	.03.K	Supervision	K					
28.	IX.05	Transportation (To include only the person shipping)	K/O					
29.	X.05, X.06	Labeling and Tagging (Other than receiving)	K/O					
30.	X.07	Shipping Documents and Records	K	3	XX	X		

SP=Shucker-Packer; SS=Shellstock Shipper; SS/WS=Shellstock Shipper with Approved Wet Storage; RS=Reshipper; DP=Depuration Processor

C=Critical; K=Key; O=Other